



American Cyanamid Company
One Cyanamid Plaza
Wayne, NJ 07470

(A)

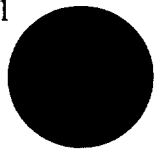
JEHQ-95-13351
46950000 1403

H. Michael D. Utidjian, M.D.
Corporate Medical Director

Document Processing Center (TS-790)
Office of Toxic Substances
U.S. Environmental Protection Agency
401 M Street S.W.
Washington, DC 20460

January 27, 1995
Study # 94-151

JEHQ-0295-13351s



Attention: Section 8(e) Coordinator

COMPANY SANITIZED

Dear Sir/Madam:

The purpose of this letter is to inform you, under TSCA Section 8(e), of results of an eye irritation screening study in rabbits communicated by memo on January 23, 1995. We have conducted this study on a research material, which is tentatively identified XXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXX also known as XXXXXXXXXXXX, and generically designated as a substituted butyric acid.

Compound Structure

XXX

1. Eye Irritation Screening Study in Rabbits Study 94-151

Two albino rabbits were exposed to the test material (100 mg/eye) without subsequent washing. The test material was found to be severely irritating to the eye with corneal effects beyond 7 days posttreatment.

We are currently evaluating the significance of these results. This material is under consideration for research and development as an herbicide and is a research chemical

If further information is required, please contact K.A. Traul, Ph.D. at 609-799-0400, Ext.2701.

Sincerely,

H. Michael D. Utidjian, M.D.
Corporate Medical Director

-1-
3/21/95

Support Information for Confidentiality Claims**TSCA 8(e) Submission on**

XX

1. For what period of time do you assert this claim of confidentiality? Explain why the information should remain confidential until such event or time.

Confidentiality is claimed for a period of 10 years from the date of submission pending finalization of the applications for a patent on the test material and the process for its synthesis. It is suggested that the generic name substituted butyric acid be used in reference to this 8(e) submission. The period between the synthesis of a research chemical and full determination of its uses is often quite long. It is important for an R&D organization to protect the confidentiality of its key resource library of chemicals

2. Have there been any confidentiality determinations made by the EPA, other Federal agencies or courts in connection with this information?

No.

3. Has any of the information that you are claiming as confidential been disclosed to individuals outside your company? Will it be disclosed to such persons in the future? If so, what restrictions, if any, apply to use or further disclosure of the information.

Information regarding the name and structure have not been disclosed to persons outside the company. At such time as patents are issued for the structure and the processes for synthesis of the material we do not plan to disclose such information to persons outside the company who would not be under an agreement of confidentiality regarding such information. Such persons would include laboratory or field personnel conducting studies with this material under contract to the company or expert consultants we may retain. Other persons outside the company will become informed after the above referred patents are obtained and our evaluation of the material is complete.

4. Briefly describe any physical or procedural restrictions within the company relating to the use and storage of the information you are claiming confidential. What other steps, if any, have you taken to prevent undesired disclosure of the information during its use or when an employee leaves the company.

The information has been given to only those individuals with a need to know. The information is considered "company confidential" and all employees who have access to this information are required to keep it confidential. Employees who have access to this information have signed confidentiality statements with regard to any such proprietary information.

5. Does the information claimed as confidential appear or is it referred to in any of the items listed below?

- advertising or promotional materials for the chemical or the end product containing it;
- safety data sheets or other such materials for the chemical or the end product containing it;
- professional or trade publications;
- any other media available to the public or to your competitors:

If you answered yes to any of the above questions, you must indicate where the information appears and explain why it should, nonetheless, be treated as confidential.

No.

The information that is to be held confidential about the chemical structure and name may appear in a Material Safety Data Sheet prepared by the company for distribution to company personnel and contracted cooperators who are involved in the technical evaluation of the material in various field trials. Such persons will have signed confidentiality agreements.

6. Would disclosure of this information be likely to result in substantial harm to your competitive position?

Disclosure of this information, prior to issue of the patents for the material and the processes for synthesis would jeopardize the proprietary nature of the material and would potentially cause the company to lose the advantage currently available though the fact that this information is not available to the competition in this market. The company is synthesizing and filing patents on analogs of this chemistry. Release of the information requested to be held confidential would aid competitive companies in analog synthesis. The technical attributes are still under investigation for this compound and the analogs, which may possess more favorable toxicologic characteristics. Additional use patents have also not yet been filed. Disclosure could jeopardize our patent positions in foreign countries. Although patent protection is guaranteed in the U.S. by FIFRA, there is no guarantee of protection in other countries. Further, misinterpretation or misrepresentation of these data could cause undue alarm to our customers and, thereby, damage our potential customer base. The period between the synthesis of a research chemical and full determination of its uses is often quite long. It is important for an R&D chemical organization to protect the confidentiality of its key resource library of chemicals

The use of acute toxicology data deriving from direct exposure of this species is not indicative of true exposure under use and could cause undue alarm when presented out of context.

7. If the information in question is "health and safety data" pursuant to 40 CFR part 2.306 (3) (i), do you assert that disclosure of the information you are claiming confidential would reveal:

- confidential process information;
- confidential portions of a mixture; or
- information unrelated to the effects of the substance on human health or the environment?

Aside from the chemical structure and name this submission does not reveal any information related to the process, product composition or other information unrelated to human health effects or the environment.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

H. Michael D. Utidjian, M.D.
Corporate Medical Director
American Cyanamid Company
One Cyanamid Plaza
Wayne, New Jersey 07470

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

APR 24 1995

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan
Terry R. O'Bryan
Risk Analysis Branch

Enclosure

13351A



Recycled/Recyclable
Printed with Soy/Canola Ink on paper that
contains at least 50% recycled fiber

Triage of 8(e) Submissions

Date sent to triage: 12/14/95

NON-CAP

CAP

Submission number: 13351 A

TSCA Inventory:

Y

N

D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO

AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX

SBTOX

SEN

w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX

CTOX

EPI

RTOX

GTOX

STOX/ONCO

CTOX/ONCO

IMMUNO

CYTO

NEUR

Other (FATE, EXPO, MET, etc.):

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

For Contractor Use Only

entire document:

0

1

2

pages

1-4

pages

1-4

Notes:

Red Dot

Contractor reviewer:

CPs

Date:

4/14/95

CECATS/TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA: Submission # BEHQ-0295-13351 ⁽³⁾ SEQ. A

TYPE: INT. SUPP FLWP

SUBMITTER NAME: American Cyanamid Company

SUB. DATE: 01/27/95 OTS DATE: 02/07/95 CSRAD DATE: 03/21/95

CHEMICAL NAME:

butyric acid, substituted

CASE#

Confident

VOLUNTARY ACTIONS:

- 0401 NO ACTION REPORTED
- 0402 STUDIES PLANNED/IN PROGRESS
- 0403 NOTIFICATION OF WORKING METHODS
- 0404 LABEL/MSDS CHANGES
- 0405 PROCESS/HANDLING CHANGES
- 0406 APPROPRIATE DISCONTINUED
- 0407 PRODUCTION DISCONTINUED
- 0408 CONFIDENTIAL

INFORMATION REQUESTED: FLWP DATE:

0501 NO INFO REQUESTED

0502 INFO REQUESTED (TECH)

0503 INFO REQUESTED (VOL ACTIONS)

0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:

0503 REFER TO CHEMICAL SCREENING

0504 CAP NOTICE

INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C
0201 ONCO (HUMAN)	01 02 04	0241 IMMUNO (ANIMAL)	01 02 04
0202 ONCO (ANIMAL)	01 02 04	0242 IMMUNO (HUMAN)	01 02 04
0203 CELL TRANS (IN VITRO)	01 02 04	0243 CHEM/PHYS PROP	01 02 04
0204 MUTA (IN VITRO)	01 02 04	0244 CLASTO (IN VITRO)	01 02 04
0205 MUTA (IN VIVO)	01 02 04	0245 CLASTO (ANIMAL)	01 02 04
0206 REPRO/TERATO (HUMAN)	01 02 04	0246 CLASTO (HUMAN)	01 02 04
0207 REPRO/TERATO (ANIMAL)	01 02 04	0247 DNA DAM/REPAIR	01 02 04
0208 NEURO (HUMAN)	01 02 04	0248 PROD/USE/PROC	01 02 04
0209 NEURO (ANIMAL)	01 02 04	0251 MSDS	01 02 04
0210 ACUTE TOX. (HUMAN)	01 02 04	0299 OTHER	01 02 04
0211 CHR. TOX. (HUMAN)	01 02 04		
0212 ACUTE TOX. (ANIMAL)	01 02 04		
0213 SUB ACUTE TOX (ANIMAL)	01 02 04		
0214 SUB CHRONIC TOX (ANIMAL)	01 02 04		
0215 CHRONIC TOX (ANIMAL)	01 02 04		

USE:

2-0

herbicide

TOXICOLOGICAL CONCERN:

LOW

MED

HIGH

SPECIES

RET

ONGOING REVIEW

YES (DROP/REFER)

NO (CONTINUE)

REFER

TRIAGE DATA NON-CBI INVENTORY

YES

NO

IN IT INQUIRY

CAS SR

Non-CBI

13351A

H

Eye irritation in the rabbit is of high concern. Application of 100 mg to one unwashed eye of two albino rabbits resulted in severe irritation with corneal effects persisting to 7 days. No other study details are available.